Attorney's Docket No. 032720-005

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
Jeffrey W. Jacobs et al.	)	Group Art Unit: 1626
Application No.: 09/738,859	)	Examiner: Taofiq A. Solola
Filed: December 13, 2000	)	Confirmation No.: 9769
For: Novel Succinate Compounds, Compositions and Methods of Use and Preparation	)	

TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231
PETITION BRANCH

Sir:

These documents are submitted in order to Petition the Commissioner to Withdraw Requirement for Restriction Under 37 CFR §§ 1.144 and 1.181

Enclosed please find:

[X] Petition from Requirement for Restriction under 37 CFR §§ 1.144 and 1.181

[X] A Petition for One Month Extension of Time.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

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Date: April 3, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
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Jeffrey W. Jacobs et al.	)	Group Art Unit: 1262
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PETITION FROM REQUIREMENT FOR RESTRICTION UNDER 37 C.F.R. §§ 1.144 AND 1.181

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants hereby petition the Commissioner under the provisions of 37 C.F.R. §§1.144 and 1.181 to review and withdraw the restriction requirement maintained in the above-identified patent application.

The above-identified application claims novel succinate compounds, pharmaceutical compositions comprising these compounds, and methods of treatment using these compounds. The application includes 162 examples of compounds synthesized, which are within the claims as originally filed. A copy of claim 1 as originally filed, as well as claim 1 as amended in a response filed on December 18, 2002, are attached in Appendix A, for the Commissioner's convenience.

Petitioner notes that a first restriction requirement was issued on April 8, 2002. This requirement was traversed in a response filed on June 10, 2002. The restriction requirement was then repeated and made final in the Office Action mailed on July 19, 2002. As required by 37 C.F.R. §1.144, reconsideration of the restriction requirement has been requested and this requirement has been repeated and made final.

As required by 37 C.F.R. §1.181(b), below is a *Statement of Facts*, *Points to be Reviewed* and *Action Requested.*

STATEMENT OF FACTS:

The Examiner issued a restriction requirement on April 8, 2002 setting forth restriction among seven groups of claims. The action also requested that if Applicants wished to elect a compound not represented by any of the groups specified, that the Applicants should elect a single disclosed species and the Examiner would then build a generic claim accordingly.

Applicants filed a response on June 10, 2002, traversing the restriction requirement. Specifically, Applicants argued that the restriction requirement was in error because under the statute (35 U.S.C. § 121, MPEP 802 and 803), restriction is appropriate when two or more independent and distinct inventions are claimed in one application. Even though the Examiner asserted that the inventions of Groups I - VII as set forth were independent and distinct, each from the other because there was no patentable co-action among the various groups, Applicants presented evidence that there appeared to be direct overlap among the compounds of Groups I - VII. Applicants asserted that since there was direct overlap among the compounds of the different Groups, which the examiner had set forth, it was an improper restriction requirement. Since there appeared to be direct overlap among the Groups I – VII, it was impossible to determine in which group a given compound belonged.

Specifically, Applicants argued that Groups I, II, V, and VI appeared to overlap as follows:

> **Group I** includes compounds of formula I, wherein **Y can be C, n is 2 or 3** and containing **benzodioxane** as a heterocyclic substituent;
>
> **Group II** includes compounds of formula I wherein **Y is C, n is 2 or 3**, and containing **benzodioxane** as a heterocyclic substituent;
>
> **Group V** includes compounds of formula I wherein **Y is C, n is 2 or 3**, and containing **benzodioxane** as a heterocyclic substituent; and
>
> **Group VI** includes compounds of formula I wherein **Y is C, n can be 2**, and containing **benzodioxane** as a heterocyclic substituent.

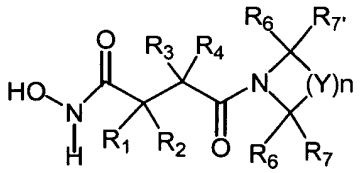
As a further example, Applicants argued that Groups I and VII appeared to overlap as follows:

> **Group I** includes compounds of formula I, wherein **Y can be N, n can be 2** and containing **benzodioxane** as a heterocyclic substituent and
>
> **Group VII** includes compounds of formula I wherein **Y is N, n is 2** and containing **benzodioxane** as a heterocyclic substituent.

Applicants maintained and continue to maintain that since there is direct overlap among the compounds of the different Groups, which the examiner has set forth, it is an improper restriction requirement.

Nevertheless, in order to comply with the requirements of 37 C.F.R. § 1.143, Applicants provisionally elected the compound of example 140. Applicants were unable to identify in which group the compound belonged or even if the there was a group in which the compound belonged.

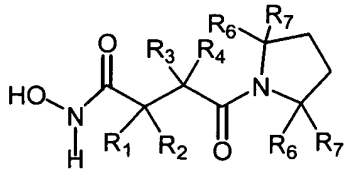
The Examiner issued a non-final office action on July 19, 2002, acknowledging election of the compound of example 140 with traversal but deeming the previous restriction proper and making it final. The Examiner indicated that the compound of example 140 did not fall within any of his previously set forth groups and indicated that the claims would be allowable if amended to recite a compound of Formula (I)



wherein a new group $R_{7'}$ (instead of R_7 as Applicants had drafted the claim) was defined by the Examiner as $-C(O)NR_{14}R_{15}$, where R_{14} is a pyridine ring attached at the 2-position, Y was to be limited to C, n was to be limited to 2, and all references to heterocycles in R_1 to R_7 and R_{15} were to be deleted.

The application was personally interviewed with Examiner Solola on October 10, 2002; however, an agreement as to permissible claim scope was not reached.

Applicants filed a response on December 18, 2002, amending the claims to define that the ring formed by N and (Y) is a pyrrolidinyl, namely n is two and Y is $-CH_2-$. Accordingly, the compounds as claimed include a hydroxamic acid functionality at one terminus linked by succinate functionality to a pyrolindinyl ring at the other terminus as illustrated by Formula I below:



Applicants maintained and continue to maintain that compounds, as defined above, clearly evidence unity of invention and define a group of compounds that can be readily searched.

In the response filed, Applicants argued that the restriction requirement as maintained necessitates the dissection of Applicant's claim 1 into countless groups and, therefore, constitutes a refusal on the part of the Office to examine the claim that Applicants believe to best represent their invention. Applicants submitted that it is improper for the Office to refuse to examine that which Applicants regard as their invention unless the subject matter of the claims lacks unity of invention. Unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature.

Applicants submitted that with regard to a common utility, the compounds of the presently claimed invention are used for the treatment of a disease treatable by administration of a peptidyl deformylase inhibitor, in particular bacterial diseases. (Specification, page 6, lines 12-28; claims 47 and 48). With regard to a substantial structural feature, the compounds as presently claimed share a common backbone as defined by Formula (I), which includes a hydroxamic acid functionality at one terminus of the backbone linked by succinate functionality to a pyrrolidinyl ring at the other terminus. This recited structure provides a common structural backbone that is a substantial structural feature, and can be readily searched without serious burden.

Applicants noted that they would be willing to file divisional applications for each combination of Y and each value of *n* in order to define a common structural backbone that can be readily searched.

The Examiner issued a final Office Action on January 22, 2003, closing prosecution on the merits and maintaining his dissection of claim 1 into compounds wherein a new group $R_{7'}$ is $-C(O)NR_{14}R_{15}$, where R_{14} is a pyridine ring attached at the 2-position, Y is C, n is 2, and all references to heterocycles in R_1 to R_7 and R_{15} are deleted. In the Office Action, the Examiner asserted that

> ... applicant is claiming numerous heterocyclic rings at position R7, each representing different sub-groups of species. The ring [at this position] determines the class and subclass that must be searched to determine novelty. Each class and subclass in the instant invention would constitute an undue burden on the Examiner. Applicant further contends that the invention share substantial structural feature. It is not relevant to novelty because other applicants may present the same invention with different structural formulae. Therefore, searching the classes and subclasses is the best way to determine novelty.

Office Action dated January 23, 2002, page 2. It is from this final Office Action which Applicants petition the Commissioner.

POINTS TO BE REVIEWED

Restriction Requirement as Maintained is Improper

Applicants respectfully assert that the restriction requirement as maintained is improper.

Initially, Applicants respectfully assert that the original restriction requirement as set forth in the Office Action of April 8, 2002 was improper. The restriction requirement was in error because under the statute (35 U.S.C. § 121, MPEP 802 and 803), restriction is appropriate when two or more ***independent and distinct*** inventions are claimed in one application. As explained above, in their response, Applicant presented evidence that there appeared to be direct overlap among the compounds of Groups I – VII and it was impossible to determine in which group a given compound belonged. Since there is direct overlap among the Groups as defined by the Examiner, the Groups do not define independent and distinct inventions.

However, to further prosecution, Applicants amended the pending claims to recite a compound of Formula (I) that has a common backbone that includes a hydroxamic acid functionality at one terminus of the backbone linked by succinate functionality to a pyrrolidinyl ring at the other terminus. Applicants respectfully assert that the claimed compounds as amended clearly exhibit unity of invention.

Applicants submit that it is improper for the Office to refuse to examine that which Applicants regard as their invention when the subject matter of the claims exhibits unity of invention. (MPEP 803.02). Specifically, in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978), the court articulated the general proposition that:

> [A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not

inconceivable that a number of the fragments would not be described in the specification.

Id. at 331.

In view of the above and similar case law, the Patent Office has set forth a general policy regarding restriction of Markush-type claims in MPEP 803.02. According to the general policy as articulated in the MPEP, "since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, it is ***improper*** for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984)." (MPEP 803.02, emphasis added). Unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature. (MPEP 803.02).

Accordingly, Applicants submit that it is improper for the Office to refuse to examine the presently claimed invention since the presently claimed subject matter clearly evidences unity of invention. With regard to a common utility, the compounds of the present invention are used for the treatment of a disease treatable by administration of a peptidyl deformylase inhibitor, in particular bacterial diseases. (Specification, page 6, lines 12-28; claims 47 and 48). With regard to a substantial structural feature, the compounds of the present invention all share a common backbone as defined by Formula (I), which includes a hydroxamic acid functionality at one terminus of the backbone linked by succinate functionality to a pyrrolidinyl ring at the other terminus. This recited structure provides a common structural backbone that is a substantial structural feature. This common structural backbone can readily be searched without serious burden. Therefore, Applicants respectfully assert that a refusal on the part of the Office to examine the amended claim presented by Applicants is improper.

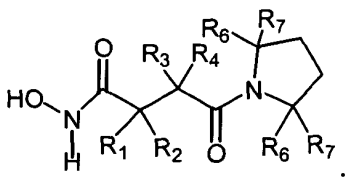
Furthermore, Applicants assert that even where a provisional election of a single species is proper prior to examination on the merits, following election the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentablity. (MPEP 803.02). The MPEP requires that should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim ***will be extended*** to non-elected species (plural). (Id.). The MPEP states that the search need not be extended unnecessarily to cover all non-elected species; however, the MPEP states that Applicant is entitled to consideration of claims to a ***reasonable number***

of disclosed species in addition to the elected species. (MPEP 809.02(b), emphasis added). Applicants disclosed 162 examples of compounds within claim 1 as originally defined. The definition of compounds that the Examiner has defined and is willing to examine only includes two of Applicants disclosed 162 compounds (the compound of Example 102 and the compound of Example 140, which was the compound elected). Applicants respectfully submit that two compounds is *not* a reasonable number of disclosed species.

Furthermore, the invention as the Examiner has defined it comprises a substituent R_{14} that is defined only as pyridin-2-yl. Accordingly, the Examiner has even omitted the compounds of Examples 58 and 59, which share the same structure as the Examiner has defined except at position R_{14}, one comprises a pyridin-3-yl (example 58) and the other comprises a pyridin-4-ylmethyl (example 59). Applicants respectfully submit that the class of compounds that the Examiner has defined is incredibly limited and as such, does not cover a reasonable number of species. Applicants further assert that this incredibly limited class of compounds is not what Applicants regard as their invention and it is ***improper*** for the Office to refuse to examine that which Applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984)." (MPEP 803.02, emphasis added).

Moreover, the Examiner states in the Office Action of January 23, 2003 that since the ring determines the class of each sub-group and the applicant is claiming numerous heterocyclic rings at position R_7, each representing different sub-groups of species, a search of the amended claim would be burdensome. However, the substituent at position R_7 is not part of the common backbone. Therefore, Applicants respectfully assert that the common backbone can be searched regardless of the substituent at position R_7.

In addition, in the Office Action of January 23, 2003, the Examiner alleges that "applicant further contends that the invention share substantial structural feature. This is not persuasive because structural representation is a choice of the applicant. It is not relevant to novelty because other applicants may present the same invention with different structural formulae." Applicants respectfully assert that the above statement is incorrect. Applicants are claiming compounds, compounds with a particular backbone as defined by the structure:



The structural representation or how the structure is presented may be somewhat a matter of choice because the compounds could also be represented, for example, as the following structure:

$$OHNHC(O)CR_1R_2CR_3R_4C(O)N(CR_6R_7)_2CH_2CH_2.$$

However, both of these are the structures clearly represent the same compounds. It is not the structural representation that should be searched but the underlying structure and the underlying structure remains the same, and it is the structure of the claimed compounds that determines novelty. To say that a structure of a compound can possibly be drawn in different representations is a part of chemistry, but the different representations ultimately provide the same compound if it is in fact just a different representation of the same compound. In addition, although compounds may be drawn in different representations, these compounds ultimately have the same structural formulae. The structural formulae are what define the compounds. Therefore, it is also incorrect to say that other applicants can present the same invention with different structural formulae – if it is a different structural formulae, it is a different compound.

In addition, Applicants believe that it is important to note that the Patent Office commonly searches compounds as defined by a Formula that recites a structural backbone, wherein the backbone itself includes a heterocyclic or carbocyclic ring, and the backbone also has various substituents defined by generic indicators, such as an R groups, the definition of which includes more than a single heterocyclic or heteroaryl. In fact, Applicants did a cursory search and found numerous patents examined by Examiner Solola, which claimed a structure having various substituents defined by generic indicators, the definition of which included more than a single heterocyclic or heteroaryl. For the Commissioners convenience, the patent numbers identified are listed in Appendix B. Since these patents reciting a structure with the possibility of more than a single heterocyclic substitutent issued, Applicants respectfully assert that it is possible to search compounds having more than a single heterocyclic substituent without serious burden and these searches are performed regularly. Accordingly, Applicants submit that it is inequitable and unjust for the Examiner to limit Applicant's claim in the manner in which he has done so. If the restriction requirement is maintained, to obtain coverage of the compounds, which Applicants regard as their invention, Applicant will be required to file countless patent applications, thus placing an unreasonable and unjust burden on the Applicants.

ACTION REQUESTED

In view of the foregoing facts and remarks, Applicants request the Commissioner to withdraw the restriction requirement as maintained in the above-identified patent application. Please contact the undersigned at (703) 838-6663 if there are any questions concerning this Petition.

Respectfully submitted,

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